DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Los Angeles District
Pacific Region
19900 MacArthur Blvd.
Suite 300
Irvine, CA 92612-2445
Telephone: 949-798-7600
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WARNING LETTER

February 10, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 22-03

Mr. Barry Pressman
Chairman
PureTek Corporation
1245 Aviation Place
San Fernando, CA 91340

Dear Mr. Pressman:

During an inspection of your manufacturing facility located in San Fernando, California conducted on December 2-5, and 12, 2002, our investigator documented deviations from the current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 351(a)(2)(B). The deviations were as follows:

1. Failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed. [21 CFR 211.192]

2. Testing and release procedures for the distribution of drug products do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release. [21 CFR 211.165(a)]

3. In-process materials are not tested for strength and approved or rejected by the quality control unit during the production process. [21 CFR 211.110(c)]

4. Each lot of components is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit. [21 CFR 211.84(a)]

5. Written calibration procedures for instruments, apparatus, gauges, and recording devices are deficient in that they do not include specific directions, schedules, limits for accuracy and precision, and provisions for remedial action if limits are not met. [21 CFR 211.160(b)(4)]

6. Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use. [21 CFR 211.63]

7. Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. [21 CFR 211.160(b)]

8. Accelerated stability studies, combined with basic stability information, used to support tentative expiration dates are not supported with ongoing full shelf life studies. [21 CFR 211.166(b)]

9. Results of stability testing are not used in determining expiration dates. [21 CFR 211.166(a)]

10. Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, but your firm does not perform at least one specific identity test on each component and establish the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals. [21 CFR 211.84(d)(2)]

11. Routine calibration, inspection, and checking of automatic equipment are not performed according to a written program designed to assure proper performance. [21 CFR 211.68(a)]

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject your products to legal action. It is your responsibility to assure that all of your products are in compliance with the Act. You should take prompt action to correct the violations observed during FDA's most recent inspection. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

We acknowledge receipt of your written response dated December 20, 2002 which responds to the Form FDA 483 issued at the conclusion of the inspection.

Our review finds that the response does not adequately address the problems specified on the Form FDA 483. Specifically, your response describes the corrective measures undertaken by your firm such as the hiring of new quality assurance personnel, commissioning validation and qualification activities of laboratory test methods and equipment, establishing new or revising existing procedures, and conducting training. It does not, however, provide sufficient documented evidence which provides a high degree of assurance that these measures will

prevent the recurrence of similar instances in the future. In some instances, your response indicates that corrective measures were undertaken but they have not been completed. In other instances, copies of documented evidence supporting your objections to certain instances as having isolate occurrences were not provided with your response. You should carefully review the situation to assure that all outstanding problems are corrected.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should describe each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and the date by which each such item will be corrected and documented

Please send your reply to the Food and Drug Administration, Director, Compliance Branch, 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445. If you have any questions regarding any issue in this letter, please contact MaryLynn Datoc, Compliance Officer at telephone number 949-798-7628.

Sincerely,

Alonza E. Cruse
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
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